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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/086,138 05/28/98 JAFFE

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HM12/0622

EXAMINER

GITOMER, R

ART UNIT	PAPER NUMBER
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1623

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DATE MAILED:

06/22/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No. <b>09/086,138</b>	Applicant(s) <b>Jaffe</b>
	Examiner <b>Ralph Gitomer</b>	Group Art Unit <b>1623</b>

Responsive to communication(s) filed on Dec 17, 1998

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 1-15 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 1-15 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 5

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

5           A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10          Claims 1, 2, 4, 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Jaffe.

Jaffe (5,387,508) by the present inventor entitled "Detection of Cytotoxic Agents Using Tetramitus Rostratus" teaches in claim 3 first paragraph, the sample may be a liquid, gaseous or solid material. Various types of whole effluent samples are taught.

All the features of the claims are taught by the reference for the same functions as claimed.

It is noted the present specification on page 2 last 20 paragraph discusses '508 where '508 does not disclose a WET test in which all of the potentially toxic substances from the sample are evaluated in a natural combination. See in '508 Example 5 in column 6 where a WET sample is tested.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

5                 (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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Claims 3, 6-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jaffe.

Jaffe (5,387,508) by the present inventor entitled "Detection of Cytotoxic Agents Using Tetramitus Rostratus" teaches in claim 3 first paragraph, the sample may be a liquid, gaseous or solid material. Various types of whole effluent samples are taught.

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The claims differ from Jaffe in that they recite other flagellates than those taught by Jaffe.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ flagellates other than T. Rostratus because in view of the teachings of Jaffe, one would have a high expectation of success in employing any known flagellate with the requisite qualities taught in the present specification. It is noted that the present specification teaches specific methods and examples only for T rostratus.

Claims 1, 2, 4, 5-15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

On page 4 of the present specification, a number of suitable flagellates are discussed. *T. Rostratus* is a preferred organism for use in the WET test of the invention. *Tetramitus*, however, is unsuitable for use in WET testing of marine water samples. On page 6 of the present specification, *T. rostratus* is combined with samples including water samples, sewage samples, industrial effluent, and ocean or estuary samples. This is unclear in view of the present claims which include marine samples.

Claims 1, 4, 7, 8, 15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for specific flagellates, does not reasonably provide enablement for any and all flagellates. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In claim 1 and all occurrences, the terms "a particle feeding flagellate" lack enablement as it would require one of ordinary skill in this art undue experimentation to determine which such flagellate would work in the instant invention.

The entire scope of the claims has not been enabled because:

1. Quantity of experimentation necessary would be undue because of the large proportion of inoperative organisms claimed.
2. Amount of direction or guidance presented is insufficient to predict which flagellates encompassed by the claims would work.
- 5 3. Presence of working examples are only for specific flagellates and extension to other flagellates has not been specifically taught or suggested.
4. The nature of the invention is complex and unpredictable.
- 10 5. State of the prior art indicates that most related flagellates are not effective for the claimed functions.
6. Level of predictability of the art is very unpredictable.
7. Breadth of the claims encompasses an innumerable number of organisms.
- 15 8. The level of one of ordinary skill in this art is variable.

In re Wands, 858 F.2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)

Claims 1-15 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant 20 regards as the invention.

In claim 1 there is inconsistency regarding if the cytotoxic substances are present or not, in step (a) the samples contains a plurality of potentially cytotoxic substances. The terms 25 "suspected of containing cytotoxic substances" is standard

terminology. In claim 7 line 4, "have been removed" may be better stated "are removed". Claim 15 is unclear in view of claim 1 from which it depends where one cannot readily determine what the flagellates are. There are many causes for them to be of different sizes including being different organisms, treated differently, etc. Where specific enablement is found in the specification for claim 15 is requested.

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

The following prior art pertinent to applicant's disclosure is made of record and not relied upon: Jaffe (Tox and Ind Health) teaches a Tetramitus assay.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (703) 308-0732. The examiner can normally be reached on Tuesday-Friday from 8:00 am - 5:00 pm. The examiner can also be reached on alternate Mondays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marian Knode, can be reached on (703) 308-

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4311. The fax phone number for this Art Unit is (703) 308-4556. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1234.

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*R. Gitomer*

Ralph Gitomer  
Primary Examiner  
Group 1623

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